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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

KERR, KATHLEEN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

20

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/824,551 | | BATHE ET AL. | |
| | Examiner | | Art Unit | |
| | Kathleen M Kerr | | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-29, 34 and 36-38 is/are allowed.
- 6) ☒ Claim(s) 20, 21, 30-33, 35 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 22 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>19</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 16, mailed on December 4, 2002), Applicants filed an amendment and response received on March 4, 2003 (Paper No. 17). Said amendment cancelled Claims 1-19 and added new Claims 20-42. Thus, Claims 20-42 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 44 755.4 filed in Germany on September 9, 2000 and for the foreign application 101 12 105.9 filed in Germany on March 14, 2001. A translation of 100 44 755.4 was filed on March 4, 2003; said priority document describes the invention claimed in Claims 20-42. Thus, the effective filing date of Claims 20-42 is September 9, 2000.

Drawings

3. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment.

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5. Previous objection to the specification for informalities is withdrawn, except for the recitation describing the drawings (maintained below), by virtue of Applicants' amendment.

Maintained - Objections to the Specification

6. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. Applicants' amendment has reduced the abstract to a description of the claims; this is improper. The Abstract should describe the entire specification, including proteins, methods, etc. Additionally, the abbreviation of the enzyme, histidine kinase (luxS), is also required for completeness as previously noted. Correction is required.
7. Previous objection to the specification for informalities is maintained with respect to the description on page 4. The description of the figure must be headed by ---Brief Description of the Drawings---, and after the description of Figure 1, the title "Detailed Description of the Invention" may be inserted. Correction is required.

Objections and Rejections of the Claims

8. All previously pending objections/rejections of the claims are withdrawn by virtue of Applicants' cancellation of all previously pending claims.

NEW OBJECTIONS/REJECTIONS

Claim Objections

9. Claim 22 is objected to for depending from a rejected claim.

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10. Claim 39 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k). The different intended use in Claims 38 and 39

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 30-32, 35, and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a polynucleotide that hybridizes to SEQ ID NO:1 (the coding strand) could encode a polypeptide having histidine kinase activity. The Examiner suggests limiting the claim to hybridizing only to the complement of SEQ ID NO:1.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 20, 21, 31, 33, and 40 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

While the specification may adequately describe the genus of polynucleotides within the % identity range or hybridization conditions claimed, the specification does not adequately describe the *subgenus* of polynucleotides within the range or conditions claimed that are *native to Corynebacterium*. In contrast, the subgenus belonging to *C. glutamicum* (Claims 22 and 32) does have adequate written description considering the limited members of the claimed genus and how well the disclosed species (SEQ ID NO:1) represents said genus as considered by those in the art.

Considering the description of all *Corynebacterium* histidine kinase genes within the structural limitations claimed from within a genus of all histidine kinase genes from any species, no particular description of coryneform DNA, in general, is found in the specification. While clearly such sequences are enabled by virtue of the skill in the art of producing DNA libraries and screening them, the structures of such sequences – in the absence of those not from

coryneform – has not been distinguished in the specification as originally filed. To obviate this rejection, the Examiner suggests deleting the phrase “native to the genus *Corynebacterium*”.

13. Claims 30-32, 35, and 41 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides hybridizing under at least, for example, high stringency conditions at 68°C, does not reasonably provide enablement for polynucleotides hybridizing under such low stringency conditions as 50°C, as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to use the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the

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relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Applicants present no guidance or working examples of the use of polynucleotides that have such low sequence identity with respect to SEQ ID NO:1. The nature of the invention is such that the DNA encodes a protein product, luxS – histidine kinase, whose attenuation is useful in the biosynthesis of L-lysine; and with such a great deviation from the known sequence, the predictability of retaining this same functionality becomes extremely low. Moreover, the instant claims are drawn to DNA sequences that encode a protein and hybridize to SEQ ID NO:1 under low stringency conditions. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

14. Claim 42 is rejected under 35 U.S.C. § 112, first paragraph, enabling deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While Applicants filed the requisite declaration concerning the availability of the deposit, the full address of the depository was not amended into the specification as required. Amendment to the specification is required. See 37 C.F.R. § 1.801 - 1.809.

Other Relevant Art

15. The following is reference as being pertinent but not prior art against the pending claims:
- a) USPAP 2002/0197605-A1 (Nakagawa *et al.*) which is the U.S. equivalent to the previously cited EP 1108790.

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) The Abstract stands objected to for not completely describing the disclosed subject matter.
 - b) The specification stands objected to for informalities with respect to the description and the Brief Description of the Drawings.
 - c) Claim 22 stands objected to for depending from a rejected claim.
 - d) Claim 39 stands objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 38.
 - e) Claims 30-32, 35, and 41 stand rejected under 35 U.S.C. § 112, second paragraph.
 - f) Claims 20, 21, 31, 33, and 40 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
 - g) Claims 30-32, 35, and 41 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
 - h) Claim 42 stands rejected under 35 U.S.C. § 112, first paragraph, enabling deposit.

Conclusion

17. Claims 23-29, 34, 36, 37, 38 are allowed in the Office action; Claims 22 and 39 are objected to; and Claims 20, 21, 30-33, 35, 40, 41, and 42 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R.


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§ 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
May 23, 2003